REMARKS

Claims 1, 2, 4, 11-16, 18-21, 23, 24, 35, 36, 38-40 and 47-55 are pending in the application. Claims 1, 18, 21, 35 and 53 are amended herein. Claims 3, 5-10, 17, 22, 25-34, 37, 41-46 were previously withdrawn from further consideration. New claims 56-72 are added herein. Claims 1, 2, 4, 11-16, 18-21, 23, 24, 35, 36, 38-40 and 47-72 remain for consideration.

Applicant appreciates the Examiner's courtesy and willingness to meet with Applicant on June 13, 2006.

Claim Rejections – 35 USC §102

35 USC §102; McDonnell

The Examiner rejects claims 1, 4, 11-16, 18, 23, 24, 35, 38-40, 47-49, 53 and 54 as being anticipated by McDonnell (U.S. Patent No. 6,126,688). The Examiner states that:

> McDonnell discloses an interbody spine fusion (10) comprising a body (18) defining an outside surface, a carrier receiving area (14), an un-doped carrier material (12), a port (16) and a pathway (see side opening in Fig. 1).
>
> Regarding claim 11, the ports 16 make the body a body-to-body appliance.
>
> Regarding claim 12, the elements 20 make the body a bone-to-device appliance.

Regarding the biologically active substances (see col. 4, lines 43-49).

Regarding claims 15 and 16 (see col. 4, lines 43-49).

Claim 1 is amended to clarify that the un-doped carrier material is loaded into said carrier receiving area to bind with a biologically active substance. McDonnell fails to teach an un-doped carrier material that binds with a biologically active substance.

The claim limitation is supported in at least the following passage, "The Carrier 310 is provided to receive bone growth accelerants, such as bone morphogenic proteins, and is located in the interior of cage 300. A preferred carrier 310 is a sponge type material such as bovine collagen sponge or any type of collagen that will bind to bone growth accelerant (lines 6–8 of ¶**[0082]**). Allowance of claim 1 is respectfully requested.

Regarding claim 2, claim 4 depends from independent claim 1, which is submitted to be patentable. Claim 2 is submitted to be patentable for at least this reason. Claim 2 is additionally submitted to be patentable over McDonnell because McDonnell fails to teach "a plug in said port adapted to be penetrated by a syringe", as is required by claim 2. Applicant could find no teachings in McDonnell related to a "plug".

Regarding claims 4, 11 and 12, claims 4, 11 and 12 each depend from independent claim 1, which is submitted to be patentable. Claims 4, 11 and 12 are submitted to be patentable for at least this reason.

Regarding claim 13, claim 13 depends from independent claim 1, which is submitted to be patentable. Claim 13 is submitted to be patentable for at least this reason. Claim 13 is additionally submitted to be patentable over McDonnell because McDonnell fails to teach a body that "comprises a cage wall having perforated zones and non-perforated zones" as required by the claim. McDonnell teaches a support structure 18 that demarcates zones on implant member 12. Each of the zones of implant member 12 is perforated. There are no "non-perforated zones" as required by the claim.

Regarding independent method claim 14, the claim is patentable over McDonnell because McDonnell fails to teach the steps of "installing a carrier into a carrier receiving area of a bone implantable device" and "applying biologcially active substance onto said carrier after said step of implanting for subsequent delivery to said target bone structure." Allowance of independent claim 14 is respectfully requested.

Regarding claim 15, the claim depends from independent claim 14, which is submitted to be patentable. Claim 15 is submitted to be patentable for at least this reason.

Regarding claim 16, the claim depends from independent claim 14, which is submitted to be patentable. Claim 16 is submitted to be patentable for at least this reason. Claim 16 is additionally patentable for the reasons set forth with respect to claim 2, above.

Claim 18 is amended to clarify that the interbody spinal fusion cage comprises a

port that communicates said outside surface with said carrier receiving area for facilitating delivery of a biologically active substance to said un-doped carrier material to bind said biologically active substance with said carrier material. McDonnell fails to teach an un-doped carrier material that binds with a biologically active substance. The claim amendment is supported at lines 6–8 of **¶[0082],** as set forth above in the discussion related to claim 1.

Regarding claim 19, the claim depends from independent claim 18, which is submitted to be patentable. Claim 19 is submitted to be patentable for at least this reason. Claim 19 is additionally patentable for the reasons set forth with respect to claim 2, above.

Regarding claim 20, the claim depends from independent claim 18, which is submitted to be patentable. Claim 20 is submitted to be patentable for at least this reason. Claim 20 is additionally patentable for at least the reason that McDonnell fails to teach at least "an end cap on an end of said cage body for enclosing said carrier receiving area", as is required by the claim.

Regarding claim 23, the claim depends from independent claim 18, which is submitted to be patentable. Claim 23 is submitted to be patentable for at least this reason.

Regarding claim 24, the claim depends from independent claim 18, which is submitted to be patentable. Claim 24 is submitted to be patentable for at least this reason.

Claim 24 is additionally patentable for the reasons set forth with respect to claim 13, above.

Regarding claim 35, Claim 35 is amended to clarify that the implantable device comprises an un-doped carrier material loaded in the carrier receiving area, said un-doped carrier material to bind to a biologically active substance. McDonnell fails to teach an un-doped carrier material that binds with a biologically active substance. The claim amendment is supported at lines 6–8 of **¶[0082],** as set forth above in the discussion related to claim 1.

Regarding claim 36, the claim depends indirectly from independent claim 35, which is submitted to be patentable. Claim 36 is submitted to be patentable for at least this reason. Claim 36 is additionally patentable for the reasons set forth with respect to claim 2, above.

Regarding independent claim 38, claim 38 is amended to clarify that the bone implantable device comprises a pre-loaded carrier material in said carrier receiving area, said pre-loaded carrier material comprising a fluidal biologically active substance." McDonnell fails to teach a fluidal biologically active substance. The claim amendment is supported at least in paragraph **[0083]**, e.g., "After the cage 300 is located, bone growth accelerant may be carefully administered via a syringe needle, which is pushed through plug 308. ... Additionally, the bone growth accelerant may be pre-loaded onto the carrier material 310 in a dissolvable form, e.g., ... gel ...". Allowance of claim 38 is respectfully

requested.

Regarding claims 39, 40, 47 and 48, these claims depend from independent claim 38, which is submitted to be patentable. Claims 39, 40, 47 and 48 are submitted to be patentable for at least this reason.

Regarding claim 49, claim 49 depends from independent claim 38, which is submitted to be patentable. Claim 49 is submitted to be patentable for at least this reason. Claim 49 is additionally submitted to be patentable over McDonnell because McDonnell fails to teach a body that "comprises a cage wall having perforated zones and non-perforated zones" as required by the claim. McDonnell teaches a support structure 18 that demarcates zones on implant member 12. Each of the zones of implant member 12 is perforated. There are no "non-perforated zones" as required by the claim.

Regarding claims 50, 51 and 52, these claims depend from independent claim 38, which is submitted to be patentable. Claims 50, 51 and 52 are submitted to be patentable for at least this reason. Claims 50, 51 and 52 are is additionally submitted to be patentable over McDonnell because McDonnell fails to teach a biologically active substance that comprises a dissolvable material, a crystalline material, or a gel material as is required by claims 50, 51 and 52, respectively.

Regarding independent claim 53, claim 53 is amended to clarify that the biologically

active substance is "fluidal". Claim 53 is submitted to be patentable for at least the reasons set forth with respect to claim 38, above. Claim 53 is additionally submitted to be patentable for the reason that claim 53 is amended to add the limitation, "but otherwise confining the biologically active substance within the device."

McDonnell is incapable of facilitating migration of a biologically active substance into contact with a target bone but otherwise confining the biologically substance within the device. This is because McDonnell teaches apertures around the perimeter of the device (McDonnell's FIG. 1). In contrast, Applicant teaches a device that has perforated and non-perforated zones used in combination with an occluding surface 148 (Applicant's FIG. 7).

The amendments to claim 53 is supported paragraph **[0083]** and in lines 6-8 of **¶[0063]**.

Regarding claims 54 and 55, the claims depend from independent claim 53, which is submitted to be patentable. Claims 54 and 55 are submitted to be patentable for at least this reason. Claims 54 and 55 are is additionally submitted to be patentable over McDonnell because McDonnell fails to teach migration of a biologically active substance that is promoted by body fluid contact or by body heat, as is required by the claim language of claims 54 and 55, respectively.

35 USC §102; Weber et al.

The Examiner rejects claims 1, 2, 18, 19, 35 and 36 as being anticipated by Weber et al. (U.S. Patent No. 6,482,234). The Examiner states that:

> Weber et al discloses a spinal disc (20) comprising a body (24), a carrier receiving area (22), an un-doped carrier material (76), a port (aperture used to insert element 72), a pathway (slit used to insert syringe, see Fig. 7B) and a plug (72).

Independent claims 1, 18 and 35 are distinguishable over the Weber et al. reference for at least the reason that the claims require:

> a [an un-doped] carrier receiving area defined by said [cage] body;
> a pathway that communicates with said carrier receiving area for delivering said biologically active substance from said carrier receiving area to a target bone structure;

The Examiner has construed materials 76 as an un-doped carrier material. However, Weber et al. teaches no "carrier material" of any kind. Weber et al.'s "materials 76" are "used for inflating the nucleus" (col. 7, line 37), not carrying a substance.

Weber et al. also teaches that, "a syringe 70 filled with any of the materials used for inflating the nucleus described above, or other materials as would be apparent to those skilled in the art as a result of the description herein . . .". However, Weber et al. teaches away from the selection of a carrier material as required by Applicant's claim 1. For example, Weber et al. expressly teaches introducing a "central supporting fluid or gel" (col.

2, line 67; col. 3, line 45), rather than a carrier material. Further, Weber et al. discusses the fact that it is *undesirable* for material to "extrude through little holes along the periphery of the disk" (see, col. 6, lines 54–65), which teaches away from the claimed element, "a pathway ... for delivering said biologically active substance from said carrier receiving area to a target bone structure".

While Weber et al. does discuss the use of growth factors, Weber et al. only contemplates incorporating growth factors into the polymer surrounding or within the holes in the polymer (see, col. 6, lines 47-52). Weber et al. does not discuss doping a carrier material with growth factors, i.e., "delivery of a biologically active substance onto said un-doped carrier material".

For at least the above reasons, Applicant requests allowance of claims 1, 18 and 35 over Weber et al.

Regarding claims 2, 19 and 36, claims 2, 19 and 36 depend from claims 1, 18 and 35, respectively, which are submitted to be patentable over Weber et al. Claims 2, 19 and 36 are submitted to be patentable for at least this reason.

35 USC §102; Camino et al.

The Examiner rejects claims 18 and 20 as being anticipated by Camino et al. (U.S. Patent No. 6,776,798). The Examiner states that:

> Camino et al discloses an interbody spine fusion (12) comprising a body (42) defining an outside surface, a carrier receiving area (32), an un-doped carrier material (see col. 4, lines 28- 32), a port (see opening at the distal end of element 12), a pathway (44) and an end cap (10).

The Examiner has construed "passageway 32" as the carrier receiving area. Camino et al. teach that, "Spacer 12 houses bone ... such that spacer 12 fuses to spine 14 to where there will be generally no movement between spacer 12 and spine 14 ...".

Camino et al., however, teach no "carrier material" as specified by the claim and further Camino et al., teach no "port that communicates said outside surface with said carrier receiving area for facilitating delivery of a biologically active substance onto said un-doped carrier material" as required by the claim.

In Camino et al., the bone housed by the spacer is both the "biologically active substance" and the "carrier material". Therefore, it is impossible for Camino et al. to anticipate the invention claimed in Applicant's claim 18.

Claim 20 depends from independent claim 18, which is submitted to be patentable. Claim 20 is submitted to be patentable for at least this reason.

Claim Rejections – 35 USC §103; McDonnell

The Examiner rejects claims 50-52 and 55 as being unpatentable over McDonnell. The Examiner states that:

> McDonnell discloses the invention substantially as claimed. However, McDonnell does not disclose the biologically active dissolvable, crystalline, a gel material and the migration of the biologically active substance is promoted by body heat.
>
> At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the composition of the biologically active substance because Applicant has not disclosed that the difference in the composition provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with McDonnell composition because it would perform equally as well.
>
> Therefore, it would have been an obvious matter of design choice to modify the McDonnell reference to obtain the invention as specified in claims 50-52 and 55.

Applicant respectfully disagrees with the Examiner. Applicant has disclosed that the difference in composition of the biologically active substance provides an advantage. In particular, Applicant directs the Examiner to lines 6–9 of paragraph **[0092]**, which states,

> Alternatively, avoiding inadvertent contact with non-target bone structures may be achieved in each of the above examples by pre-loading devices with a dissolvable form of bone growth accelerant that liquefies after exposure to an implanted environment.

Applicant requests allowance of claims 50–52 and 55.

Allowable Subject Matter

The Examiner objects to claim 21 as being dependent upon a rejected base claim. The Examiner states the claim, " ... would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims".

Claim 21 is rewritten in independent form to include all of the limitations of base claim 18 and intervening claim 20. Claim 21 is further amended to replace "syringe" with –delivery device--.

New Claims

New independent claims 56 and 57 add the limitation of a "substantially solid end cap", which is not taught by any of the cited references, and which is supported at least in paragraphs **[0020]**, **[0072]**, **[0075]**.

New independent claims 58, 60 and 64 add the limitation that the "un-doped carrier material" is an "un-doped collagen carrier material", which is not taught by any of the cited references, and which is supported at least in paragraph **[0083]**.

New independent claims 62 and 66 add the limitations that the "un-doped material" is an "un-doped sponge material", which is not taught by any of the cited

references, and which is supported at least in paragraph **[0083]**.

New independent claim 70 adds the limitation that the carrier is doped with a dissolvable biologically active substance that liquefies after contact with the body fluids, which is not taught by any of the cited references, and which is supported at least in paragraph **[0072]**.

New independent claim 71 contains limitations directed to a "fluidal" bone growth agent and also specifies that migration of the fluidal bone growth agent to the target bone growth structure is facilitated by otherwise confining the bone growth agent with said device. Applicant teaches a device that has perforated and non-perforated zones used in combination with an occluding surface 148 (Applicant's FIG. 7), paragraph **[0083]** and in lines 6-8 of ¶**[0063]**.

New dependent claim 72 specifies that the delivery device of claim 21 may be a syringe.

Considering the foregoing, it is sincerely believed that this case is in condition for allowance, which is respectfully requested.

This paper is intended to constitute a complete response to the outstanding Office Action. Please contact the undersigned if it appears that a portion of this response is missing or if there remain any additional matters to resolve. If the Examiner feels that processing of the application can be expedited in any respect by a personal conference, please consider this an invitation to contact the undersigned by phone.

Respectfully submitted,

Date: 6-26-06

James F. Lea III, Reg. No. 41,143

FELLERS, SNIDER, BLANKENSHIP,
BAILEY & TIPPENS, P.C.
321 South Boston Ave., Suite 800
Tulsa, Oklahoma 74103-3318
(918) 599-0621

ATTORNEYS FOR APPLICANT

Customer Number: 22206

W357344.2